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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,299	03/12/2004	Gerald Horn	114309-1017	7833
7590 BELL, BOYD & LLOYD LLC P.O. Box 1135 Chicago, IL 60690-1135			EXAMINER HAND, MELANIE JO	
		ART UNIT 3761	PAPER NUMBER PAPER	
		MAIL DATE 10/18/2007	DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/799,299	HORN, GERALD
	Examiner Melanie J. Hand	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 July 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 33-36 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 33-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/26/07
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

Applicant's arguments with respect to claims 28-32 have been considered but are moot in view of the cancellation of those claims.

With respect to applicant's arguments regarding the prior art of Gluchowski: Applicant argues that the emphasis of the Gluchowski formulation is directed to reducing or maintaining intraocular pressure in mammalian animals, whereas the claimed invention is concerned with reducing pupil size. This is not found persuasive. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As to applicant's argument that Gluchowski does not teach a therapeutically effective amount, applicant only discloses several disparate and discrete amounts of active ingredient as examples, which is not sufficient disclosure

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gluchowski (U.S. Patent No. 5,252,295) in view of any of Lowry (U.S. Patent No. 5,981,563), Samour et al (U.S. Patent No. 5,942,545) and Gerstenberg et al (U.S. Patent No. 5,236,904).

With respect to **claim 33**: Gluchowski teaches an ophthalmic formulation, comprising: a sterile aqueous carrier in the form of saline; and a pharmaceutically active compound consisting essentially of an imidazoline in a therapeutically effective amount. (Col. 4, lines 5-8, 15-20) The limitation "to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness" constitutes functional language that is given little patentable weight herein.

Gluchowski does not teach a pharmaceutically active compound consisting essentially of phentolamine. However phentolamine is an imidazoline that is known in the art as an alpha receptor antagonist that is used to treat sexual dysfunction by its control of vasodilation as supported by Lowry, Samour et al and Gerstenberg et al. Applicant states in the Specification that alpha 1 antagonists such as phentolamine that are used to treat sexual dysfunction (interpreted herein as "those known in the art for treating sexual dysfunction") can be used as the claimed pharmaceutically active compound of the claimed invention. (Specification, Page 3, line 29 – Page 4, line 4) Therefore it would be obvious to one of ordinary skill in the art to modify the formulation of Gluchowski such that the imidazoline is phentolamine with a reasonable expectation of success, as phentolamine as an alpha 1 receptor antagonist controls the degree of iris dilation (or contraction in environments with less light), which results in control of pupil contraction.

With respect to **claim 34**: Gluchowski teaches that the active agent is present in an amount between 0.0001-1% weight by volume solvent (g/cc). Gluchowski teaches a composition having 300 ml water, therefore the active agent is present in an amount between 30-3,000 mg/cc, which overlaps the range set forth in claim 34. (Col. 4, lines 20-25, Col. 12, lines 48-50)

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With respect to **claim 35**: The sterile aqueous carrier taught by Gluchowski comprises saline, which is an ophthalmic artificial tear solution. (Col. 4, lines 5-7)

With respect to **claim 36**: The formulation fairly suggested by Gluchowski meets all of the claim limitations of claim 36. With respect to the limitation "the pupil is effectively reduced by 1.0 mm or more", this limitation is considered herein to also be fairly suggested by Gluchowski as being an inherent property of the formulation consisting essentially of phentolamine that is fairly suggested by Gluchowski. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01). A *prima facie* case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, an ophthalmic formulation comprising a carrier and active compound present in the claimed amount) except for a property or function (in the present case, the amount by which the pupil is effectively reduced) and the examiner can not determine whether or not the reference inherently possesses properties that render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

September 25, 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

